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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,408

11/30/2006

Leander Grode

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7590

04/24/2009

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WASHINGTON, DC 20005

EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

04/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No. 10/554,408	Applicant(s) GRODE ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 6-32 is/are allowed.
- 6) ☒ Claim(s) 5 and 39-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. **THE FINALITY OF THE LAST OFFICE ACTION IS HEREBY VACATED.**
2. Applicants' Response to Office Action, received 9 March 2009, is acknowledged.
3. Claims 1-32 and 39-46 are pending and under consideration.

Rejections Withdrawn

4. The rejection of claims 18-20 and 31 under 35 U.S.C. 112, second paragraph, as being indefinite for function of second peptide or polypeptide immune response, is withdrawn in light of applicants' argument.

Rejections Maintained

5. The rejection of claims 39-46 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is

Applicants argue that the specification provides a clear description of using the claimed method to treat mice and guinea pigs, i.e., mammals, infected with *M. tuberculosis* and *M. bovis* BCG, i.e., disease states which would convey to those skilled in the art that the inventors did have possession of the invention at the time of filing and that there is sufficient written description for claim 40, directed to treating a mammal with tuberculosis, claim 41, drawn to the claimed method in immunodeficient mammals, claim 42, drawn to HIV, claim 43, drawn to tumor and claim 44, drawn to superficial bladder cancer disease state.

The examiner has considered applicants' arguments, but does not find them persuasive for the reasons put forth in the original rejection.

Claim 39 is a method of treating a mammal having a disease state, comprising administering to the mammal a bacterial cell which is urease-deficient and which comprises: 1)

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a recombinant nucleic acid molecule encoding a fusion polypeptide comprising ≥ 1 domain from a polypeptide, wherein said polypeptide domain is capable of eliciting "an" immune response in a mammal, and, 2) a phagolysosomal escape domain, in a pharmaceutically effective amount.

According to this claim, one can utilize any polypeptide domain, regardless of source, to treat any disease state. The capability of the domain to elicit "an" immune response is not restricted to an immune response to the disease state, but can be any immune response.

Claim 40 is the method of claim 39, wherein the disease state is tuberculosis. While the disease state is now confined to tuberculosis, there is no such restriction on the polypeptide domain to have any relationship to tuberculosis. Thus, the claim is a method of treating tuberculosis by utilizing any polypeptide domain, regardless of source.

Claim 41 is the method of claim 39, wherein the mammal is immunodeficient. As in claim 39, the method is drawn to treating any disease state by utilizing any polypeptide regardless of source.

Claim 42 is the method of claim 41, wherein the disease state is HIV. While the disease state is now confined to HIV, there is no such restriction on the polypeptide domain to have any relationship to HIV. Thus, the claim is a method of treating HIV by utilizing any polypeptide domain, regardless of source.

Claim 43 is the method of claim 39 wherein said mammal has a tumor and the administration of said bacterial cell treats the tumor. There is no restriction on the polypeptide domain to have any relationship to said tumor. Thus, the claim is a method of treating tumor by utilizing any polypeptide domain, regardless of source.

Claim 44 is the method of claim 39 wherein the disease state is superficial bladder cancer. While the disease state is now confined to superficial bladder cancer, there is no such

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restriction on the polypeptide domain to have any relationship to superficial bladder cancer.

Thus, the claim is a method of treating superficial bladder cancer by utilizing any polypeptide domain, regardless of source.

Claims 45 and 46 are identical to claim 39, except that said mammal is an animal or a human. According to these claims, one can utilize any polypeptide domain, regardless of source, to treat any disease state. The capability of the domain to elicit "an" immune response is not restricted to an immune response to the disease state, but can be any immune response.

Therefor, the claims remain containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed method for treating any mammal having any disease state by administering a urease-deficient bacterial cell comprising a recombinant nucleic acid encoding for any polypeptide.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Embodiment (c) of claim 5 is drawn to "a nucleotide sequence hybridizing under stringent conditions with the sequence from (a) or (b).

Claim 5 is vague and indefinite because the phrase "hybridizing under stringent conditions" is vague and indefinite because hybridization conditions can vary considerably. A number of parameters govern the stringency of the hybridization including the hybridization

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temperature, hybridization time, washing temperature, washing time, formamide concentration, detergent concentration, and salt concentration. Changes in these parameters will affect the specificity of the binding. Thus, in order to ascertain the metes and bounds of the patent protection, the skilled artisan would require a knowledge of these specific parameters. The claim does not clearly and unambiguously set forth the appropriate reaction conditions. The rejection may be overcome by clearly setting forth in the claim the reaction conditions encompassed by a stringent hybridization, as supported by the disclosure.

Conclusion

8. Claims 5 and 39-46 are rejected.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 14, 2009